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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,940	10/10/2000	Shi Kun Huang	5325-0166.30	6690

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

15

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/685,940

**Applicant(s)**

HUANG ET AL.

**Examiner**

Gollamudi S Kishore, PhD

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### DETAILED ACTION

The petition (1.137 b), the amendment and the formal drawings filed on 6-30-03 are acknowledged.

Claims included in the prosecution are 1-18 and 30-33.

#### *Claim Rejections - 35 USC ' 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 3718 of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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2. Claims 1-3, 5-15, and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolff (5,965,434) of record.

Wolf discloses liposomal compositions containing instant compounds where L is an ester and Z is either imidazole or an amino group. The liposomes carry either polypeptides or nucleic acids for transfection. The liposomes further include targeting ligand (note the abstract, columns 5-19 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant amends claim 1 and argue that Wolff et al nowhere show a structure where the linkage between the pH sensitive group and the hydrophobic moiety is identical to the present linker. This argument is not found to be persuasive. According to instant claim 1, L can be  $-X-CH_2-$ . According to claim 2, X is NH and Y is oxygen. The structures 1-3, 8 meet the requirements of instant claims. The rejection is maintained.

*Claim Rejections - 35 USC ' 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-3, 5-15, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above.

In Wolff,  $n$  is 1; however, instant compounds where  $n$  is more than 1 (claims recite 1-20) are homologues and it would have been obvious to one of ordinary skill in the art to prepare liposomes containing compounds where  $n$  is more than one since homologues are expected to behave the same way.

5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above, further in view of Allen 96,056,973).

The teachings of Wolff have been discussed above. What are lacking in Wolff are the teachings of FGF as the targeting ligand.

Allen while disclosing liposomal compositions containing therapeutic agents, teaches that liposomes can be targeted to tumor cells by inclusion of targeting ligands such as FGF (note the abstract, col. 11, lines 45-53).

The inclusion of targeting ligand such as FGF in the liposomal compositions of Wolff would have been obvious to one of ordinary skill in the art since with such an inclusion, one could target tumor cells as taught by Allen.

6. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above, further in view of Zalipsky (5,395,619) of record.

Wolff does not teach the inclusion of a lipid derivatized with PEG.

Zalipsky while disclosing liposome formulations teaches that inclusion of a polymer-lipid conjugate will extend the circulation time of the liposome by several fold (note the abstract and col. 8, lines 45-53).

The inclusion of a polymer-lipid conjugate in the liposomes of Wolff would have been obvious to one of ordinary skill in the art since such an inclusion would extend the circulation time of the liposomes as taught by Zalipsky.

Applicant's arguments to the above rejections have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on apparent different structure taught by Wolff. This issue has been addressed above. The references of Allen, and Zalipsky have been added for their teachings of targeting ligands and polymer-lipid conjugates respectively and applicant provides no specific arguments with regard to these secondary references.

Claim 4 is objected to as being dependent on the rejected base claim 1. Claim 4 is allowable if written in independent form.

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1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD  
Primary Examiner  
Art Unit 1615

GSK